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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: 510-337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 20-85116

November 4, 1996

James S. Nace
16026 Road 64
Tipton, CA 93272

WARNING LETTER

Dear Mr. Nace:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on June 27 and July 1, 1996, by Food and Drug Administration (FDA) Investigator Christopher J. Lee have revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(D) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On April 22, 1996, you consigned two dairy cows (identified by USDA laboratory report numbers 367816 and 384831) which were sold for slaughter as human food. These cows were delivered for introduction into interstate commerce by your firm and were adulterated by the presence of illegal drug residues. USDA analysis of tissues for the animal noted in report number 367816 revealed the presence of sulfadimethoxine in the liver at 1.60 parts per million (ppm) and in the muscle at 2.90 ppm. Analysis for the animal under report number 384831 revealed sulfadimethoxine in the liver at 0.84 ppm and in the muscle at 0.57 ppm. The tolerance level for sulfadimethoxine in the edible tissues of cattle has been established at 0.1 ppm.

Your firm has established a history of offering animals for sale for human food use which have been found to be adulterated due to the presence of drug residues. According to USDA analytical reports, during the period of December 22, 1987 to March 29, 1995, your firm delivered eighteen cows and one calf which were found to contain illegal drug residues.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health". As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.

4. You lack an adequate system for determining that quantities of drugs are being accounted for to prevent the possible overdosing of animals.

The Albon brand sulfadimethoxine boluses that you use to treat your dairy cows are adulterated under Section 501(a)(5) of the Act, in that they are new animal drugs within the meaning of Section 201(w) and are unsafe within the meaning of Section 512(a)(1)(B) since they are not being used in conformance with approved labeling. Labeling for Albon prescribes two boluses followed by one bolus per day for three to four days. Labeling also requires a seven day withdrawal period prior to slaughter for food use. Failure to adhere to the prescribed withdrawal time is likely the cause of the presence of violative levels of sulfadimethoxine in the tissues of the animals you sold for food use. Failure to comply with the label instructions on a drug presents the likely possibility that illegal residues will occur and makes the drug unsafe to use.

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act and regulations are being met. You were informed of the same violations in a Warning Letter issued on April 18, 1994. The letter was issued as a result of an investigation involving the overdosing of a dairy cow with penicillin. Your firm has failed to take adequate corrective action. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should include copies of any available documentation demonstrating that corrections have been made. Please direct your reply to John M. Reves, Compliance Officer.

Sincerely yours,

Patricia C. Ziobro

Patricia C. Ziobro
District Director
San Francisco District

cc: [redacted]